

REMARKS

Claims 30, 31, 33-38 and 44-49 are pending in the application. Claims 30 and 31 stand rejected under 35 U.S.C. 102(b) as being anticipated by Cragg (2001/49527). Claims 44 and 45 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Cragg '527 in view of Froning (3875595). Claims 33-38 and 46-49 have been indicated to be allowable if rewritten to include all the limitations of the base claim and any intervening claims. Favorable reconsideration of the application is respectfully requested.

1. Claims 30-31 and 44-45.

In applicants' response to the Office Action mailed September 5, 2006, applicants traversed the pending rejection on the basis that Cragg '527 does not disclose implanting a whole disc annulus in an intervertebral disc nucleus space. Since the current Office Action reiterated that rejection and further stated that applicants' prior response "failed to distinguish how the claims avoid the Cragg reference," applicants will restate the reasons previously given as to why it is believed that the cited prior art does not teach the claimed invention.

The initial focus of a §102 rejection must be on the pending claims. Here, claim 31 is the relevant base claim, and it states:

31. A method of augmenting or replacing an intervertebral disc nucleus, said method comprising the steps of:

- (a) providing an intervertebral disc implant comprising allogenic or xenogenic disc annulus material that is substantially free of both disc nucleus material and disc endplate material; and
- (b) implanting said intervertebral disc implant in an intervertebral disc nucleus space;
 - wherein said intervertebral disc implant comprises allogenic or xenogenic disc annulus material that comprises a whole disc annulus.

As stated in applicants' prior Response, claim 31 differs from Cragg '527 at least by the fact that Cragg '527 does not disclose implanting a whole disc annulus into an intervertebral disc space as presently claimed. Instead, Cragg discloses implanting a nondescript "biomaterial" into a disc space, where the disc space may include its original annulus which functions as an envelope to contain the biomaterial.

The Office's contention that paragraph 174 of Cragg '527 discloses implanting a whole disc annulus into a disc space is believed to be in error. The relevant language of paragraph 174 of Cragg '527 states:

In addition, it is also possible to augment a spinal disc by introducing one or more artificial spinal disc implant or other biomaterials to provide a functional disc replacement implant or bone growth materials to effect fusion into the void or cavity that is made within the annulus AF, thereby employing the annulus AF to retain the introduced implants or biomaterials or fusion enhancing materials in place. The annulus AF can itself be used as an envelope to contain the delivered disc augmentation materials comprising spinal disc implant(s), bone growth material or other biomaterials. Optionally, means are provided to contain the disc augmentation materials within the desired space, e.g., by delivering the disc augmentation materials into an additional envelope within the cavity as described above with reference to FIGs. 17 - 20. (Emphasis added.)

It can be seen from the above that paragraph 174 of Cragg '527 does not teach implanting a whole disc annulus in an intervertebral disc nucleus space. Instead, that paragraph merely teaches implanting "one or more artificial spinal disc implant or other biomaterials" into a disc annulus. The annulus referred to in paragraph 174 is the annulus of the disc being repaired, and is not the biomaterial being implanted.

Moreover, the remainder of the Cragg '527 publication fails to teach using a whole disc annulus as a disc implant material. In that regard perhaps the most relevant portion of Cragg '527 is paragraph 160, which states:

In this case, the biomaterial filling the envelope 80 is a material that is capable of being introduced to the site of a joint by minimally invasive means, and be hydrated or cured in place to provide desired physical-chemical properties as described, for example, in the above-referenced '326, '454, '220 and '736 patents. A hydrogel can be injected into the envelope 80 in a liquid or dry particulate form or in microspheres or beads in the manner shown in FIG. 18. A preferred hydrogel is formulated as a mixture of hydrogel polyacrylonitrile or any hydrophilic acrylate derivative with a unique multiblock copolymer structure or any other hydrogel material having the ability to imbibe and expel fluids while maintaining its structure under various stresses. For example, the hydrogel can be formulated as a mixture of polyvinyl alcohol and water. The hydrogel core formed within the envelope 80 will swell as it absorbs fluids through the porous fabric wall of the envelope 80 much like a native nucleus. The hydrogel core has a time constant of swelling which is highly similar to that of the natural nucleus and will thus experience a 5-30% and preferably a 15-20% volume change depending on load over the course of 2-8 (preferably 4-8) hours. When fully hydrated, the hydrogel core will have a water content of between 25-65%. The hydrogel material of the preferred embodiment is manufactured under the trade name Hypan.RTM. by Hymedix International, Inc. In addition, any of the hydrogels and solvents identified in the above-referenced '326 patent may be employed to fill the envelope 80.

In view of the above it is respectfully submitted that the cited prior art does not teach implanting a whole disc annulus into an intervertebral disc nucleus space as required by the pending claims. Accordingly, the rejection under §102 should be withdrawn.

As to the claims rejected under §103 based on Cragg in view of Froning, since Cragg does not teach or suggest the implantation of a whole disc annulus as indicated above, the stated rejections should be withdrawn.

2. Claims 33-38 and 46-49.

By this amendment/response claims 33-38 and 46-49 have been rewritten to include all the limitations of the base claim and any intervening claims. The allowance of those claims is therefore respectfully requested.

3. New claims 101-104.

New claims 101-104 restate original claims 46-49 before the present amendments. Since claims 31 and 44 are believed to be patentable for the reasons stated above, new claims 101-104 are also believed to be patentable over the cited prior art.

In view of the above, it is respectfully submitted that all pending claims are allowable over the prior art of record. Passage of the pending claims to allowance is therefore respectfully requested.

Respectfully submitted,

By Timothy N. Thomas
Timothy N. Thomas, Esq.,
Reg. No. 35,714
Woodard, Emhardt, Moriarty, McNett & Henry LLP
111 Monument Circle, Suite 3700
Indianapolis, IN 46204-5137
(317) 634-3456 Telephone
(317) 637-7561 Facsimile

Attorney for Applicants